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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/820,441

Applicant(s)

CAMPBELL ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 and 30-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28 and 30-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/9/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the RCE filed 4/24/2007. Claims 25, 30, 32, and 36 are amended. Amendments to the drawings and specification are acknowledged. **Claims 25-28 and 30-42** remain pending.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ultrasonic imaging arrangement disposed *on or about the distal end* of the elongated member, said ultrasonic imaging arrangement comprising *a rotatable ultrasonic imaging transducer coupled to a rotatable shaft that extends proximally to the proximal end of the elongated member* of **Claims 25-28 and 30-42** (especially **Claims 31 and 40**) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The Examiner notes that although the new drawings submitted 4/24/2007 do show an ultrasonic imaging arrangement, the details of its positioning and components are not shown as claimed above. Furthermore, it is noted that in the new drawings ultrasonic imaging arrangement is shown displaced *away* from said elongated member and it is not understood how said ultrasonic imaging arrangement can collect imaging data when it is not even connected to the elongated member to be inserted in the body.

Double Patenting

4. In light of the claim amendments, the previous nonstatutory obviousness-type double patenting rejection over Claim 5 of US Pat No. 6245026 is withdrawn at the present time.

Claim Rejections - 35 USC § 112

5. The previous §112 rejections are withdrawn in light of Applicant's arguments dated 4/24/2007 and the newly submitted drawings also filed 4/24/2007.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 25-27, 30, 32, 35-39, and 41-42** are rejected under 35 U.S.C. 102(e) as being anticipated by Casscells III et al (US Pat No. 6615071).

8. In regard to **Claims 25 and 36**, Casscells III et al disclose a system for thermally mapping a vessel wall in the body of a patient comprising:

an elongated member (210) suitable for insertion in a vessel of a body of a patient, the elongated member having a proximal and a distal end (232), best seen in Figure 23;

an expansion device (230) disposed at or about the distal end of the elongated member (Col.30: 1-28);

at least one thermal sensor (220, 260) capable of detecting relatively small temperature variations on the vessel wall (Col.31: 50-52), the at least one thermal sensor disposed on the expansion device wherein the expansion device is thereby capable of positioning the at least one thermal sensor against the vessel wall (Col.30: 1-28);

an ultrasonic imaging arrangement disposed on or about the distal end of the elongated member (Col.30: 63-67; Col.31: 1-14);

a control circuitry which receives and processes signals from the at least one thermal sensor and the ultrasonic imaging arrangement and merges the signals to generate an image of a portion of the vessel wall (Col.28: 50-53; Col.31: 1-14);

a display (Col.28: 50-53) coupled to the control circuitry and arranged to receive the merged signals and to graphically display the image of the portion of the vessel wall, wherein the image comprises a thermal map showing temperature variations along a portion of the vessel wall (Col.31: 6-14), best seen in Figures 28B-C.

9. In regard to **Claims 26 and 38**, Casscells III et al disclose the at least one thermal sensor (220) comprises a plurality of thermal sensors (260) arranged in a band disposed about the distal section of the elongate shaft, best seen in Figure 23 (Col.30: 9-12; Col.31: 29-65).

10. In regard to **Claims 27 and 37**, Casscells III et al disclose the at least one thermal sensor is selected from the group consisting of an infrared sensor, a thermocouple, and a thermistor.

11. In regard to **Claims 30 and 39**, Casscells III et al disclose the ultrasonic imaging arrangement comprises an ultrasonic transducer (Col.31: 1-5).

12. In regard to **Claims 32 and 41**, Casscells III et al disclose the at least one thermal sensor and the ultrasonic imaging arrangement are disposed adjacent each other.

13. In regard to **Claims 35 and 42**, Casscells III et al disclose the expansion device is a radially expansible balloon (Col.31: 62-65).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 25-27, 30, 32-34, 36-39, and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana et al (US Pat No. 6176842) in view of Casscells III et al (US Pat No. 6615071).

16. In regard to **Claims 25 and 36**, Tachibana et al disclose a system for thermally mapping a vessel wall in the body of a patient comprising:

an elongated member (14) suitable for insertion in a vessel of a body of a patient, the elongated member having a proximal and a distal end;

an expansion device (12, 30) disposed at or about the distal end of the elongated member;

at least one thermal sensor (22) capable of detecting relatively small temperature variations on the vessel wall, the at least one thermal sensor disposed on the expansion device wherein the expansion device is thereby capable of positioning the at least one thermal sensor against the vessel wall;

a control circuitry (100) which receives and processes signals from the at least one thermal sensor;

a display (102) coupled to the control circuitry and arranged to receive information from the thermal sensor and to graphically display a thermal map showing temperature variations along a portion of the vessel wall, best seen in Figure 16 (Col.25: 10-16).

17. However, Tachibana et al do not disclose an ultrasonic imaging arrangement disposed on or about the distal end of the elongated member and the control circuitry receives and processes signals from the ultrasonic imaging arrangement and merges the signals to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall.

18. Casscells III et al disclose an analogous device comprising an ultrasonic imaging arrangement or “ultrasound transducer” disposed on or about the distal end of an elongated member with control circuitry to receive and process signals from the ultrasonic imaging arrangement and merges the signals with signals from a thermal sensor to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall, best seen in Figures 28B-C (Col.31: 1-14) to provide an improved thermosensing catheter.

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Tachibana et al to include an ultrasonic imaging arrangement disposed on or about the distal end of the elongated member and the control circuitry receives and processes signals from the ultrasonic imaging arrangement along with the thermal signals and merges the signals to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall as taught by Casscells III et al to provide an improved thermosensing catheter.

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20. In regard to **Claims 26 and 38**, Tachibana et al disclose the at least one thermal sensor (22) comprises a plurality of thermal sensors arranged in a band disposed about the distal section of the elongate shaft, best seen in Figure 1B.

21. In regard to **Claims 27 and 37**, Tachibana et al disclose the at least one thermal sensor is selected from the group consisting of an infrared sensor, a thermocouple, and a thermistor (Col.24: 30-35).

22. In regard to **Claims 30 and 39**, Casscells III et al disclose the ultrasonic imaging arrangement comprises an ultrasonic transducer (Col.31: 1-5).

23. In regard to **Claims 32 and 41**, Tachibana et al and Casscells III et al disclose the at least one thermal sensor and the ultrasonic imaging arrangement are disposed adjacent each other.

24. In regards to **Claim 33**, Tachibana et al disclose at least a first flow altering member (30a) on the elongated member adjacent the at least one thermal sensor (22), best seen in Figure 8.

25. In regards to **Claim 34**, Tachibana et al disclose at least a second flow altering member (30b) on the elongated member adjacent the at least one thermal sensor (22), the at least one thermal sensor being positioned on the elongated member between the first flow altering member (30a) and the second flow altering member, best seen in Figure 8.

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26. **Claim 25-27, 30, 35, 36-39, and 42** are rejected under 35 U.S.C. 102(b) as being unpatentable over Stern et al (US Pat No. 5443470) in view of Casscells III et al.

27. In regard to **Claims 25 and 36**, Stern et al disclose a system for thermally mapping a vessel wall in the body of a patient comprising:

an elongated member (16) suitable for insertion in a vessel of a body of a patient, the elongated member having a proximal and a distal end;

an expansion device (14, 39) disposed at or about the distal end of the elongated member;

at least one thermal sensor (24, 42) capable of detecting relatively small temperature variations on the vessel wall, the at least one thermal sensor disposed on the expansion device wherein the expansion device is thereby capable of positioning the at least one thermal sensor against the vessel wall (Col.4: 59-60);

a control circuitry (128) which receives and processes signals from the at least one thermal sensor;

a display included with computer (114) coupled to the control circuitry and arranged to receive information from the thermal sensor and capable of graphically display a thermal map showing temperature variations along a portion of the vessel wall, best seen in Figure 5 and 12.

28. However, Stern et al do not disclose an ultrasonic imaging arrangement disposed on or about the distal end of the elongated member and the control circuitry receives and processes signals from the ultrasonic imaging arrangement and merges the signals to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall.

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29. Casscells III et al disclose an analogous device comprising an ultrasonic imaging arrangement or “ultrasound transducer” disposed on or about the distal end of an elongated member with control circuitry to receive and process signals from the ultrasonic imaging arrangement and merges the signals with signals from a thermal sensor to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall, best seen in Figures 28B-C (Col.31: 1-14) to provide an improved thermosensing catheter.

30. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stern et al to include an ultrasonic imaging arrangement disposed on or about the distal end of the elongated member and the control circuitry receives and processes signals from the ultrasonic imaging arrangement along with the thermal signals and merges the signals to generate an image of a portion of the vessel wall which is displayed to comprise a thermal map showing temperature variations along the portion of the vessel wall as taught by Casscells III et al to provide an improved thermosensing catheter.

31. In regard to **Claims 26 and 38**, Stern et al disclose the at least one thermal sensor (24, 42) comprises a plurality of thermal sensors arranged in a band disposed about the distal section of the elongate shaft, best seen in Figure 1 and 4.

32. In regard to **Claims 27 and 37**, Stern et al disclose the at least one thermal sensor (24, 42) is selected from the group consisting of an infrared sensor, a thermocouple, and a thermistor (Col.4: 62-66).

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33. In regards to **Claims 30 and 39**, Casscells III et al disclose the ultrasonic imaging arrangement comprises an ultrasonic transducer (Col.31: 1-5).

34. In regard to **Claims 35 and 42**, Stern et al disclose the expansion device (14, 39) is a radially expansible balloon.

35. **Claims 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells III et al, or Tachibana et al or Stern et al in view of Casscells III et al, further in view of vanHooydonk (US Pat No. 5902251).

36. Casscells III et al or Tachibana et al or Stern et al in combination with Casscells III et al disclose the invention above but do not disclose said display shows a color coded thermal map. VanHooydonk disclose an analogous apparatus comprising a display that graphically displays a thermal map from thermal sensors color coded such that temperature of tissue is indicated by the color on the display as an effective method to communicate the thermal data (Col.16: 42-47).

37. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Casscells III et al or Tachibana et al or Stern et al as modified by Casscells III et al so that the graphical display of the thermal map is color coded such that temperature of tissue graphically displayed is indicated by the color of the tissue on the display as taught by vanHooydonk as an effective means to relay said thermal information.

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38. **Claims 31 and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Casscells III et al, or Tachibana et al or Stern et al in view of Casscells III et al, further in view of Pomeranz (US Pat No. 5558093).

39. Casscells III et al or Tachibana et al or Stern et al in combination with Casscells III et al disclose the apparatus described above but do not disclose said ultrasonic imaging arrangement comprises a rotatable ultrasonic imaging transducer coupled to a rotatable shaft that extends proximally. Pomeranz teaches of an ultrasonic imaging arrangement comprising a rotatable ultrasonic transducer (32, 64) coupled to a rotatable shaft (24, 54) that extends proximally as an effective imaging device and can be used with other devices analogous to the invention of Stern et al (Col.7: 44-45). Pomeranz also discloses said imaging apparatus comprising a control circuit (102) to receive signals from said imaging apparatus and a display (108) coupled to said control circuit to display an image of what is scanned (Col.5: 3-5, 40-42), as disclosed in US Pat No.4794931, incorporated by reference by Pomeranz (Col.6: 63-64).

40. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Casscells III et al or Tachibana et al or Stern et al as modified by Casscells III et al to include an ultrasonic imaging arrangement comprising a rotatable ultrasonic transducer coupled to a rotatable shaft that extends proximally, as taught by Pomeranz, as an effective ultrasonic imaging arrangement.

Response to Arguments

41. Applicant's arguments with respect to claims 25-28 and 30-42 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
5/29/2007



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